ISRCTN12356200 https://doi.org/10.1186/ISRCTN12356200

The clinical efficacy of hydrogen combined with tetrandrine in the treatment of silicosis fibrosis

Submission date 22/09/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [X] Individual participant data [_] Record updated in last year
Registration date 23/09/2025	**Overall study status** Completed	
Last Edited 23/09/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
This study looked at whether combining hydrogen inhalation with a medicine called tetrandrine could help people with stage II silicosis, a lung disease caused by breathing in dust over many years. The researchers wanted to see if this combination could improve lung function, exercise ability, and symptoms better than tetrandrine alone.

Who can participate?
Adults aged 50 to 80 years old who had been diagnosed with stage II silicosis and had at least five years of dust exposure could take part. People with certain other health conditions, such as tuberculosis, severe chronic obstructive pulmonary disease, serious kidney or liver problems, or cancer, were not included.

What does the study involve?
Participants were randomly assigned to one of two groups. One group received tetrandrine tablets and inhaled a mixture of oxygen and nitrogen. The other group received tetrandrine tablets and inhaled a mixture of oxygen and hydrogen. Both treatments lasted for several months. The researchers measured lung function, exercise ability, symptoms, and blood markers before and after treatment.

What are the possible benefits and risks of participating?
The possible benefit was improved lung function and symptoms for people with silicosis. As with any medical study, there could be risks from the treatments or side effects from the medicines, but these were monitored by the study team.

Where is the study run from?
The study was run at the Laizhou Chronic Disease Prevention and Treatment Hospital in Laizhou City, Shandong Province, China.

When is the study starting and how long is it expected to run for?
October 2023 to September 2025.

who is funding the study?
Laizhou Chronic Disease Prevention and Treatment Hospital (China)

who is the main contact?
Dr Kang Xiao, cpuokkkkk@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Kang Xiao

Contact details
No 18877 Jingshi Road, Lixia District Jinan, Jinan 250062, Shandong, People's Republic of China
Ji'nan
China
250062
+86 13770992028
cpuokkkkk@163.com

Additional identifiers

Study information

Scientific Title
Observation on the clinical efficacy of hydrogen-oxygen aerosol inhalation in the treatment of pneumoconiosis

Study objectives
We aim to evaluate the efficacy between tetrandrine (Tet) alone and in combination with hydrogen (H2) inhalation in patients with stage II silicosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/08/2023, Lai Zhou City Chronic Disease Prevention and Control Hospital Ethics Committee (NO 738 Wenhua east Road, Laizhou City, Shandong, Laizhou City, 261400, China; +86 134 0535 5531; 1228297211@qq.com), ref: NO.MXBFZY-2023-03

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied
Silicosis

Interventions
We used blocking randomisation. Staff other than participants, care providers, outcome assessors, data analysts generated the random allocation sequence. Random numbers include 1 and 2.The patients were evenly divided into 6 groups based on their smoking status. Each group of patients drew lots to determine their group assignment. Those who drew odd numbers were assigned to the control group, while those who drew even numbers were assigned to the treatment group. The treatment plan for each research subject is generated by a randomly assigned sequence and is placed in an ordered, sealed, and opaque envelope. The envelope can only be opened when a qualified subject agrees to participate in the trial, and then the subject can receive the corresponding treatment measures. The personnel who enrolled and those who assigned participants to the interventions could not access to the random allocation sequence. Participants, care providers, outcome assessors, data analysts were blinded after assignment to interventions. To ensure the implementation of blinding, the same hydrogen-oxygen machine and control machine were used for the experiment.

Control group: Tetrandrine oral administration, 60mg, tid, for 6 consecutive days, followed by a 1-day break combined with mixture of oxygen (33%) and nitrogen (67%) (flow: 3L/min) inhalation 2h per day.
Treatment group: Tetrandrine oral administration, 60mg, tid, for 6 consecutive days, followed by a 1-day break combined with mixture of oxygen (33%) and hydrogen (67%) (flow: 3L/min) inhalation 2h per day.

Intervention Type
Device

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Hydrogen-oxygen machine

Primary outcome(s)
Diffusion Lung capacity for CO measured using pulmonary function testing equipment after 6 months treatment

Key secondary outcome(s)
1. Forced vital capacity measured using pulmonary function testing equipment after 3 and 6 months treatment
2. Forced expiratory volume in one second measured using pulmonary function testing equipment after 3 and 6 months treatment
3. Diffusion Lung capacity for CO measured using pulmonary function testing equipment after 3 months treatment
4. Modified Medical Research Council measured using questionnaire after 3 and 6 months treatment

5. COPD Assessment Test measured using questionnaire after 3 and 6 months treatment
6. Walking distance measured using 6 min walk experiment after 6 months treatment
7. Serum IL-6 level measured using ELISA after 3 and 6 months treatment

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Age: 50 - 80 years old, gender not restricted
2. Diagnosed with stage II silicosis based on medical history and related examinations
3. Dust exposure ≥ 5 years
4. Voluntary signing of the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
108

Key exclusion criteria
1. Patients with a history of tuberculosis or those in the active stage of tuberculosis
2. Pulmonary tumors
3. Severe chronic obstructive pulmonary disease (GOLD level 4)
4. Estimated glomerular filtration rate (eGFR) lower than 30 milliliters per minute
5. Child-Pugh B/C grade
6. Pregnant women

Date of first enrolment
23/10/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
China

Study participating centre
Laizhou Chronic Disease Prevention and Treatment Hospital
NO 738 Wenhua east Road, Laizhou City, Shandong
Laizhou City
China
261400

Sponsor information

Organisation
Laizhou Chronic Disease Prevention and Treatment Hospital, Shandong Province

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Laizhou Chronic Disease Prevention and Treatment Hospital, Shandong Province

Results and Publications

Individual participant data (IPD) sharing plan
The research results have been made public on the Dryad database. DOI: 10.5061/dryad.rfj6q57pp

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset			23/09/2025	No	No